

# **EXHIBIT F**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

*All Actions*

PLAINTIFFS' **THIRD** AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD,  
PURSUANT TO FED. R. CIV. P. 30(b)(6)

TO: Seth Goldberg, Esq.  
Duane Morris LLP  
30 South 17th Street  
Philadelphia, PA 19103-4196

*Counsel for Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this      day of November, 2020.

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**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on November , 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai US Inc., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC, and Defendants' liaison counsel, via email.

DATED this day of November, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater  
Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

**EXHIBIT A**

All topics reference information and documents known to, and/or in the possession, custody, or control of ZHP, in the ordinary course of its business.

All references to ZHP include Zhejiang Huahai Pharmaceutical Co., Ltd.

All references to Solco indicate Solco Healthcare US, LLC.

All references to Princeton indicate Princeton Pharmaceutical, Inc.

All references to Huahai indicate Huahai US, Inc.

All references to the API, ZHP's valsartan API, or ZHP's API are defined ~~as as USD MF grade~~ valsartan ~~USD MF grade~~ API manufactured, sold, or distributed by ZHP.

All references to the finished dose, ZHP's valsartan finished dose, or ZHP's finished dose are defined ~~as valsartan finished dose manufactured, sold, or distributed by ZHP. finished dose valsartan or valsartan HCTZ manufactured pursuant to ANDA 204821 and ANDA 206083, manufactured by ZHP, and sold or distributed by Solco.~~

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

In accordance with the Court's Macro Discovery Order, all references to testing are defined as testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)

- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

All references to “cGMPs” are defined to refer to cGMPs referenced in FDA correspondence and FDA documents relating to the investigation into the presence of NDMA and/or NDEA in valsartan manufactured by ZHP.

All references to “SOPs” are defined to refer to SOPs referenced in FDA correspondence and FDA documents relating to the investigation into the presence of NDMA and/or NDEA in valsartan manufactured by ZHP.

All references to “policies” or “procedures” are defined to refer to SOPs referenced in FDA correspondence and FDA documents relating to the investigation into the presence of NDMA and/or NDEA in valsartan manufactured by ZHP.

#### ***Testing of Valsartan API***

1. The cause of the contamination of ZHP’s valsartan API with nitrosamines including NDMA.
2. The root cause investigation begun in 2018 and conducted by ZHP for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
3. The testing performed by ZHP or its agents, to evaluate the purity and contents of ZHP’s API (regardless of intended sale location) manufactured in any facility that manufactured ZHP’s valsartan API for sale in the United States.
4. The testing performed by ZHP or its agents, to evaluate the purity and contents of ZHP’s finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP’s finished dose for sale in the United States.
5. The testing performed by any entity or person other than ZHP or its agents but known to ZHP, to evaluate the purity and contents of ZHP’s valsartan API (regardless of intended

- sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
6. The testing performed by any entity or person other than ZHP or its agents but known to ZHP, to evaluate the purity and contents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  7. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
  8. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  9. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
  10. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  11. ZHP's evaluation of the potential risks to the purity or contents of ZHP's valsartan API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
  12. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
  13. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  14. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the solvents utilized in the manufacture of ZHP's API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
  15. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the solvents utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  16. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the production equipment utilized in the manufacture of ZHP's valsartan API (regardless

- of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
17. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the production equipment utilized in the manufacture of ZHP's valsartan finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  18. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the production equipment utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.
  19. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the production equipment utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.
  20. The extent of the actual and potential nitrosamine contamination ~~presence of NDMA and/or NDEA of of~~ ZHP's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

21. ZHP's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.) ~~(The parties to meet and confer in an effort to identify the responsive information and documents in advance of the deposition).~~
22. ZHP's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of ZHP's valsartan finished dose (regardless of intended sale location) in any facility that manufactured ZHP's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.) ~~(The parties to meet and confer in an effort to identify the responsive information and documents in advance of the deposition).~~
23. ZHP's application of cGMPs in connection with the manufacture of ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant



- ~~cGMP's.) (The parties to meet and confer in an effort to identify the responsive information and documents in advance of the deposition).~~
24. ZHP's application of cGMPs in connection with the manufacture of ZHP's finished dose ~~(regardless of intended sale location) in any facility that manufactured ZHP's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.) (The parties to meet and confer in an effort to identify the responsive information and documents in advance of the deposition).~~
25. The "relevant SOP's, QS, testing method, validation reports, equipment calibration records, preventive maintenance plan and change control records, etc." referenced at b.6. on ZHP00004355. ~~(The parties to meet and confer in an effort to identify the responsive information and documents in advance of the deposition).~~
26. The distinction between technical inquiries and deviation reports, as those terms are defined in ZHP's documents and in the ordinary course of business.
27. The processes and procedures for handling technical inquiries.
28. The processes and procedures for handling deviation reports.
29. The technical inquiries received by ZHP relating to ZHP's valsartan API, ~~(regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.~~
30. The technical inquiries received by ZHP relating to ZHP's valsartan Finished Dose ~~(regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.~~
31. The deviation reports ~~received-drafted by~~ or received by ZHP relating to ZHP's valsartan API ~~(regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.~~
32. The deviation reports ~~received-drafted by~~ or received by ZHP relating to ZHP's valsartan Finished Dose ~~(regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.~~

**Process Development**

33. The "primary process validation of Process II (Zn cl2) completed in April 2012" referenced on ZHP00004372.
34. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API ~~(regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.~~
35. Any evaluation conducted by or on behalf of ZHP with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API ~~(regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.~~ 35A. ZHP's evaluation and knowledge of the risk of the creation of nitrosamines including

NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.

36. ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API, and ZHP's valsartan finished dose.
37. The process changes referenced in section 3.4.1 on ZHP00004371.

**Communications with Regulatory Agencies**

38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.
40. ZHP's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of the presence of NDMA and/or NDEA impurities in ZHP's valsartan API with nitrosamines including NDMA and NDEA.
41. ZHP's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.

**ZHP's Communications with API and Finished Dose Customers and Downstream Customers**

42. ZHP's oral and written communications with Novartis with regard to the content/purity/contamination of ZHP's valsartan API.
43. ZHP's oral and written communications with ZHP's valsartan API Customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan API.
44. ZHP's oral and written communications with ZHP's valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.
45. ZHP's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of ZHP's valsartan API or ZHP's valsartan finished dose.
46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.
47. All credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP in connection with the nitrosamine contamination presence of NDMA and/or NDEA of ZHP's valsartan API and ZHP's valsartan finished dose.

**Compliance with cGMPs**

48. ZHP's compliance or non-compliance with cGMPs as it relates to the manufacture, quality assurance, quality control, and sale of ZHP's API and ZHP's valsartan finished dose ~~(regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API and ZHP's valsartan finished dose for sale in the United States. (The parties to meet and confer in an effort to identify the responsive information and documents in advance of the deposition).~~
49. The "GMP and process training" referenced in the Personnel section on ZHP00004368.

**Product Tracing**

50. Tracing of batches and lots of ZHP's valsartan API sold downstream and ultimately intended for use by consumers in the United States.
51. Tracing of batches and lots of ZHP's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
52. The pricing of ZHP's valsartan API that was ultimately sold in the United States.
53. The pricing of ZHP's valsartan finished dose that was ultimately sold in the United States.
54. The gross and net profits to ZHP from the sale of ZHP's valsartan API in the United States.
55. The gross and net profits to ZHP from the sale of ZHP's valsartan finished dose in the United States.
56. The quantity/units of ZHP's valsartan API sold in the United States.
57. The quantity/units of ZHP's valsartan finished dose sold in the United States.
58. The ZHP valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided at least 3060 days in advance of deposition during the meet and confer process).
59. The ZHP valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 3060 days in advance of deposition during the meet and confer process).